

b.) Remarks

Claims 1<sup>1</sup>, 41 and 42 have been amended in order to correct typographical or grammatical errors. Additionally, claim 40 is cancelled and claims 41 and 42 are amended to maintain their dependency. The subject matter of the amendment to claim 41 is found at specification page 16, lines 11-12. Accordingly, no new matter has been added.

Claims 1-3 and 38-44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Takayuki (JP 9-285298) and Hama (WO 97/40376) in view of Miki (U.S. Patent No. 6,162,607).

As explained in the office Action from pages 3-4,

Takayuki et al. teach a method of measuring HDL-cholesterol in a specimen by treating the specimen with a cholesterol esterase and cholesterol oxidase in the presence of albumin separately derived from the specimen. Takayuki et al. teach that the specimen is treated with a polyanion such as a sulfated polysaccharide, particularly dextran sulfate, and a nonionic surfactant.

Hama et al. teach a method for specifically assaying HDL cholesterol in which serum or plasma samples having HDL cholesterol are brought into contact with cholesterol esterase, cholesterol oxidase and bile acid or its salt in the presence of albumin and ... nonionic surfactant.

Miki et al. beneficially teach that surfactants for measuring HDL, particularly nonionic surfactants such as polyoxyethylene oleyl ether, in addition to others, preferably those having HLB values from 12-17.

Therefore, in support of the rejection, the Examiner states

---

<sup>1</sup> As clarified above in amended claim 1, the process of the present invention requires correlating formed reduced coenzyme to the amount of cholesterol in high density lipoprotein.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Takayuki et al., based upon the beneficial teachings provided by Hama et al. ... and by Miki et al.

Applicants previously showed by Declaration under Rule 132 that their use of polyoxyethylene alkylamines and polyoxyethylene alkenylamines were unexpectedly superior (61.3 percent more accurate) than the closest prior art.<sup>2</sup>

In response, the Examiner now states

Applicants' Declaration does not address the teaching in Miki et al. that polyoxyethylene oleyl ether is useful as a nonionic surfactant for determining HDL cholesterol in a sample, which is a particular example given by Applicant in the instant specification of nonionic surfactants (see, for example, page 21, line 6 and page 22, lines 3-4).<sup>3</sup>

This statement is not well-understood. It is long accepted that the Declaration need only compare the present invention to the closest prior art, e.g., the Examiner's primary reference. Applicants have done just that. Nonetheless, solely in order to reduce the issues and expedite prosecution, Applicants have proceeded to make the comparisons newly-requested by the Examiner. Those comparisons are presented in the attached Declaration under Rule 132 of Yuki Katayama.

As evidenced in Mr. Katayama's Declaration, the particular nonionic surfactants of the present invention are superior to Miki's polyoxyethylene oleyl ether as

---

<sup>2</sup> E.g., polyoxyethylene octylphenyl ether, polyoxyethylene nonylphenyl ether, n-octyl- $\beta$ -D-thioglucoside and n-heptyl- $\beta$ -D-thioglucoside.

<sup>3</sup> The Examiner also notes that polyoxyethylene dodecylamine is not claimed. Respectfully submitted, the basis for this is unclear since "polyoxyethylene dodecylamine" is plainly a representative "polyoxyethylene alkylamine" (claim 1, line 7).

well. The Declaration shows that polyoxyethylene alkylamine such as polyoxyethylene dodecylamine<sup>4</sup>, polyoxyethylene octadecylamine, and polyoxyethylene alkenylamine such as polyoxyethylene oleylamine are all superior to Miki's polyoxyethylene oleyl ether. In this regard, the present invention is 50.2 percent more accurate than Miki.<sup>5</sup>

Thus, in conformity with the Examiner's request, Applicants have shown that polyoxyethylene alkylamine and polyoxyethylene alkenylamine are superior to polyoxyethylene oleyl ether.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-3, 38, 39 and 41-44 remain presented for continued prosecution.

---

<sup>4</sup> Same as polyoxyethylene laurylamine.

<sup>5</sup>  $((0.9610 + 0.9068 + 0.9695 + 0.8752)/(0.6875 + 0.6692 + 0.5120 + 0.6039)) \times 100 - 100$

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Lawrence S. Perry/

Lawrence S. Perry  
Attorney for Applicants  
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
Facsimile: (212) 218-2200

LSP\ac

FCHS\_WS 2620059\_1.DOC